Lower Passaic River Restoration Project

DATA USABILITY AND DATA EVALUATION PLAN FOR THE LOWER PASSAIC RIVER STUDY AREA RISK ASSESSMENTS

REVISED DRAFT

Prepared for:

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Table of Contents

Tables

Acronyms

ASTM	American Society for Testing and Materials
BERA	baseline ecological risk assessment
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COPC	chemical of potential concern
CPG	Cooperating Parties Group
CTE	central tendency exposure
DDD	dichlorodiphenyldichloroethane
DDE	dichlorodiphenyldichloroethylene
DDT	dichlorodiphenyltrichloroethane
DQO	data quality objective
EPC	exposure point concentration
FS	feasibility study
HHRA	human health risk assessment
HPAH	high-molecular-weight polycyclic aromatic hydrocarbon
HRGC	high-resolution gas chromatography
HRMS	high-resolution mass spectrometry
LPAH	low-molecular-weight polycyclic aromatic hydrocarbon
LPR	Lower Passaic River
LPRSA	Lower Passaic River Study Area
LRC	low-resolution coring
MEDD	multimedia electronic data deliverable
OC	organic carbon
PAH	polycyclic aromatic hydrocarbon
PCB	polychlorinated biphenyl
PCDD	polychlorinated dibenzo-*p*-dioxin
PCDF	polychlorinated dibenzofuran
PFD	problem formulation document
QA/QC	quality assurance/quality control
QAPP	quality assurance project plan

RARC	risk analysis and risk characterization
RI	remedial investigation
RL	reporting limit
RME	reasonably maximum exposed
SOP	standard operating procedure
SVOC	semivolatile organic compound
TEF	toxic equivalency factor
TEQ	toxic equivalent
TOC	total organic carbon
UCL	upper confidence limit on the mean
USEPA	US Environmental Protection Agency
WHO	World Health Organization

1 Introduction

This revised *Data Usability and Data Evaluation Plan for the Lower Passaic River Study Area Risk Assessments* describes the Lower Passaic River (LPR) Cooperating Parties Group's (CPG's) plan for evaluating the data usability for risk assessment data. This plan includes the criteria for establishing an acceptable dataset for calculating exposure estimates, including exposure point concentrations (EPCs), in the baseline human health risk assessment (HHRA) and the baseline ecological risk assessment (BERA) for the Lower Passaic River Study Area (LPRSA). This plan, along with several other technical documents, will assist in planning for the baseline risk assessments that will be developed by the CPG as described in Section 1 of the Problem Formulation Document (PFD) (Windward and AECOM 2009). The remaining risk assessment-related technical documents (as described in Section 1 of the PFD) include the following:

- *Revised Lower Passaic River Restoration Project Risk Analysis and Risk Characterization Plan for the Lower Passaic River Study Area* (Windward and AECOM [in prep]), hereafter referred to as the Revised Risk Analysis and Risk Characterization (RARC) Plan
- *Revised COPC and COPEC Selection Process for the Lower Passaic River Study Area Risk Assessments*[1]
- *Use of Urban Regional Background and Reference Conditions Data in the Lower Passaic River Study Area Risk Assessments*[2]
- *Lower Passaic River Study Area: Toxicity Reference Value Deliverable* (Windward [in prep])

Procedures for assessing the usability of data for a risk assessment and guidance for integrating data of various levels of quality from different sources into a risk assessment are provided by the US Environmental Protection Agency (USEPA) (1989, 1992a, 2002a). The criteria and requirements laid out in these USEPA documents will guide the data usability assessment for the LPRSA baseline risk assessments. A reliable, high-quality dataset that meets the data quality objectives (DQOs) of the project quality assurance project plans (QAPPs) is critical to ensuring that the results of the baseline risk assessments, required by the May 2007 Settlement Agreement (USEPA 2007), can be used in Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) decision-making.

[1] Appendix A of the Revised RARC Plan (Windward and AECOM [in prep]).
[2] Appendix B of the Revised RARC Plan (Windward and AECOM [in prep]).

Data rules and DQOs established in this plan are specifically limited to the data to be used to derive risk estimates in the LPRSA risk assessments. Data that do not meet the DQOs for use in the quantification of risks may still be used in other aspects of the LPRSA remedial investigation/feasibility study (RI/FS), including the site characterization, overall nature and extent characterization, trend analysis of chemical concentrations over time, background evaluation, and modeling.

The following data usability, reduction, and calculation topics specific to the risk assessments are discussed in this plan as follows:

- Section 2, Summary of Existing LPRSA Data
- Section 3, Risk Assessment DQOs
- Section 4, Risk Assessment Data Reduction Rules
- Section 5, Risk Assessment Data Calculation Rules

2 Summary of Existing LPRSA Data

As described in the PFD (Windward and AECOM 2009), the lower 8 miles of the LPRSA have been extensively sampled since 1990 during numerous investigation programs conducted by various agencies and organizations. More recent investigations have also included the collection of sediment and surface water samples along the entire 17.4-mile LPRSA.

The entire 17.4-mile LPRSA has been under investigation by the CPG since 2007; investigations conducted by the CPG have included the collection of sediment and tissue chemistry samples, biological community surveys and habitat assessments, surface water monitoring, bathymetric surveys (up to approximately River Mile 15), and aerial photography. For the purpose of this plan, two different groups of data are identified: data collected by CPG since 2007 ("CPG data"), and data collected by "other parties." These two classes of data are summarized in the following subsections.

2.1 Existing and Future CPG Datasets

Several data collection activities have been implemented by the CPG since the beginning of the CPG-led LPRSA RI (initiated in 2007); these field efforts have included the collection of numerous site-specific data, including sediment chemistry/toxicity, water quality, fish/ decapod and benthic invertebrate tissue chemistry, benthic community, fish community, and avian data. These assessments have followed the overarching sampling design presented in the *Lower Passaic River Restoration Project Draft Field Sampling Plan, Volume 2* (Malcolm Pirnie et al. 2006), which was prepared for USEPA and its Partner Agencies. The objectives of the CPG-led sampling activities are presented in the following USEPA-approved QAPPs, which

were prepared using the Uniform Federal Policy for QAPP guidance (USEPA et al. 2005):

- The *Lower Passaic River Restoration Project RI Low-Resolution Coring/Sediment Sampling Quality Assurance Project Plan* (ENSR et al. 2008)
- The *Lower Passaic River Restoration Project RI Water Column Monitoring/Physical Data Collection Quality Assurance Project Plan/Field Sampling Plan Addendum* (AECOM 2009)
- The *Lower Passaic River Restoration Project Fish and Decapod Crustacean Tissue Collection for Chemical Analysis and Fish Community Survey Quality Assurance Project Plan* (Windward 2009a), hereafter referred to as the Fish/Decapod QAPP
- The *Lower Passaic River Restoration Project Surface Sediment Chemical Analysis and Benthic Invertebrate Toxicity and Bioaccumulation Testing* Quality Assurance Project Plan (Windward 2009b), hereafter referred to as the Benthic QAPP
- *Lower Passaic River Restoration Project, Lower Passaic River Study Area RI/FS, Winter 2010 Fish Community Survey. Addendum to the Quality Assurance Project Plan: Fish and Decapod Crustacean Tissue Collection for Chemical Analysis and Fish Community Survey. Addendum No. 1. Final* (Windward 2010g)
- *Lower Passaic River Restoration Project, Lower Passaic River Study Area RI/FS, Avian Community Survey. Addendum to the Quality Assurance Project Plan: Fish and Decapod Crustacean Tissue Collection for Chemical Analysis and Fish Community Survey. Addendum No. 2. Final* (Windward 2010a)
- *Lower Passaic River Restoration Project, Lower Passaic River Study Area RI/FS, Late Spring/Early Summer 2010 Fish Community Survey. Addendum to the Quality Assurance Project Plan: Fish and Decapod Crustacean Tissue Collection for Chemical Analysis and Fish Community Survey. Addendum No. 3. Final* (Windward 2010d)
- *Lower Passaic River Restoration Project, Lower Passaic River Study Area RI/FS, Late Spring/Early Summer 2010 Fish Tissue Collection, Addendum to the Quality Assurance Project Plan: Fish and Decapod Crustacean Tissue Collection for Chemical Analysis and Fish Community Survey. Addendum No. 4. Final* (Windward 2010e)
- *Lower Passaic River Restoration Project, Lower Passaic River Study Area RI/FS, Spring and Summer 2010 Benthic Invertebrate Community Surveys, Addendum to the Quality Assurance Project Plan: Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing. Addendum No. 1. Final* (Windward 2010f)
- *Lower Passaic River Restoration Project, Lower Passaic River Study Area RI/FS, Collection of Surface Sediment Samples Co-Located with Small Forage Fish Tissue Samples. Addendum to the Quality Assurance Project Plan: Surface Sediment*

Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing. Addendum No. 2. Final (Windward 2010b)

- *Lower Passaic River Restoration Project, Lower Passaic River Study Area RI/FS, Habitat Identification Survey. Addendum to the Quality Assurance Project Plan: Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing. Addendum No. 3. Final* (Windward 2010c)
- *Quality Assurance Project Plan/Field Sampling Plan Addendum, Remedial Investigation Water Column Monitoring/Physical Data Collection for the Lower Passaic River, Newark Bay and Wet Weather Monitoring, Lower Passaic River Restoration Project* (AECOM 2010)
- *Combined Sewer Overflow/Stormwater Outfall Investigation Quality Assurance Project Plan, Lower Passaic River Study Area* (Tierra Solutions 2011)
- *Lower Passaic River Restoration Project, Lower Passaic River Study Area RI/FS, Caged Bivalve Study, Addendum to the Quality Assurance Project Plan: Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing. Addendum No. 4. Final* (Windward 2011)
- *Quality Assurance Project Plan/Field Sampling Plan Addendum, Remedial Investigation Water Column Monitoring/Small Volume Chemical Data Collection, Lower Passaic River Restoration Project* (AECOM 2011a)
- *Quality Assurance Project Plan: River Mile 10.9 Characterization, Lower Passaic River Restoration Project* (AECOM 2011b)
- *Lower Passaic River Study Area, Low Resolution Coring Supplemental Sampling Program, Quality Assurance Project Plan* (AECOM [in prep]-a)
- *Lower Passaic River Restoration Project, Quality Assurance Project Plan, River Mile 10.9 Hydrodynamic Field Investigation for the Lower Passaic River* (AECOM [in prep]-b)
- *Quality Assurance Project Plan/Field Sampling Plan Addendum, Remedial Investigation Water Column Monitoring/High Volume Chemical Data Collection, Lower Passaic River Restoration Project* (AECOM ([in prep]-c)

These QAPPs specified DQOs that were consistent with USEPA guidance to ensure that the data collected were of sufficient quality to support the RI, including the risk assessments. The relevant data (i.e., sediment chemistry, sediment toxicity, sediment bioaccumulation, benthic community, fish/decapod tissue chemistry, surface water chemistry, fish community) that have been and will be collected in accordance with these QAPPs and any QAPP addenda, will be used to estimate potential risks, provided that these data meet the DQOs outlined in this document. During the December 14 and December 16, 2010, meetings between USEPA and CPG representatives, it was agreed that EPCs in the risk assessments will be calculated

using only current (CPG) data that meet the DQOs specified in this document. Older data may be considered, however, when evaluating nature and extent and time-related trends.

2.2 DATA COLLECTED BY OTHER PARTIES

Most of the LPRSA data collected by parties other than CPG were noted in the PFD (Windward and AECOM 2009) and are described elsewhere (Battelle 2005, 2007; Malcolm Pirnie 2007a, b, c; Tierra Solutions 2003, 2004). Data collected by other parties included the following types of data:

- Chemistry data (biota tissue, surface sediment, and surface water)
- Benthic sediment toxicity data
- Biological data (i.e., community data)
- Physical and habitat data

As outlined in a letter submitted to USEPA (de maximis 2010), the various databases (e.g., PREmis) are not reliable or usable for evaluation in their current conditions. USEPA is currently updating the PREmis database to address these issues.

During the December 14 and December 16, 2010, meetings between USEPA and CPG representatives, it was agreed that older data and data collected by other parties may be used for other aspects of the RI to provide perspective on current and historical conditions, evaluate trends in chemical concentrations, and/or augment the current dataset to further characterize the nature and extent of contamination in the LPRSA but will not be used quantitatively to derive risk estimates in the risk assessments. A discussion of older data, including an evaluation of concentration trends, will be included in the risk assessments and the RI report.

3 Risk Assessment DQOs

Any data used in the LPRSA baseline risk assessments to define potential exposure and/or estimate potential risks (i.e., EPCs based on chemistry data or metrics based on toxicity or community data) will undergo an evaluation to determine if the quality of the data is appropriate for the intended data use. The DQO review process will be documented in a format consistent with the data usability worksheets provided in USEPA Risk Assessment Guidance for Superfund, Part D (EPA 1999). USEPA risk assessment guidance (USEPA 1992a) identifies data usability criteria and provides a useful framework for assessing data quality and the uncertainties associated with the data to be used in human health and ecological risk assessments. As noted in this guidance, a key step in the process of evaluating data usability is assessing whether DQOs were met. DQOs are typically established for large and complex investigations such as an RI. Selecting appropriate risk assessment- specific DQOs ensures that the

data used to characterize ecological and human health risks are representative, reliable, accurate, and relevant. DQOs provide all parties with a common benchmark to determine the acceptability of data used to derive risk estimates and develop risk-based goals that ultimately are used in making remedial decisions.

The following subsections present the DQOs that will be used to determine the acceptability of chemistry, toxicity, and benthic community data for use in the evaluation of potential risks. All data that have been or will be collected by the CPG will be evaluated using these DQOs. Data that do not meet the DQOs for use in the derivation of EPCs in the risk assessments may still be evaluated for other aspects of the LPRSA RI/FS, such as site characterization, nature and extent, trend analysis of chemical concentrations over time, or background evaluation, and modeling.

Five general levels for defining/applying risk assessment DQOs were identified: event, station, sample, result, and validation. These DQOs are applicable to all data types and are presented in the following subsections.

3.1 EVENT LEVEL

Two event-level DQOs were identified:

Event-Level DQO No. 1 – Original hard copies or electronic copies of data report(s) must be available. Verification of the contents of electronic datasets is necessary[3] and requires a review of the original data report. A review of field and laboratory methods is also critical to the usability determination and requires access to original information. If electronic datasets cannot be verified, the data may still be used (and flagged as uncertain) in other aspects of the RI. They will not, however, be used to calculate EPCs or derive estimates of potential risks in the risk assessments.

Event Level-DQO No. 2 – Data must be representative of current conditions. Numerous data have been collected from the LPRSA within the past 20 years; however, data collected during the most recent collection efforts are likely to be more representative of current conditions. Per the agreement between USEPA and CPG, only data collected by CPG since 2007 will be considered to be representative of current conditions within the LPRSA and used in evaluating potential risks in the baseline risk assessments. Older data or data that do not meet the specified DQOs may be used in the evaluation of other aspects of the RI/FS (e.g., in the trend analysis), but not in deriving risk estimates in the baseline risk assessments.

[3] A minimum of 20% of the data will be verified against hard copy or electronic data report(s).

3.2 STATION LEVEL

Two station-level DQOs were identified:

Station-Level DQO No. 1 – Sediment should not have been dredged[4] or capped since sample collection. Sediment characterization, as part of the RI or remedial pre-design, generally precedes remediation. If the sediment has been dredged or capped after samples were taken, data from these areas will not be considered acceptable for use in the risk assessments because sediments that have been remediated or dredged no longer reflect current conditions.

Station-Level DQO No. 2 – Field coordinates must be available to verify where data were collected. Data that are intended for use in the risk assessments will be associated with coordinates based on differential global positioning system or standard survey methods. Data that do not require coordinates (e.g., trawl transects) or have less-precise location information will be considered in the risk assessments when broader spatial risk characterization is appropriate. Only data collected from within the LPRSA (defined as the 17.4-mile stretch of the LPRSA from Dundee Dam to Newark Bay and the LPRSA tributaries to the head of tide) will be used to estimate potential risks.

3.3 SAMPLE LEVEL

Two sample-level DQOs were identified:

Sample-Level DQO No. 1 – Sample depth interval must be identified. For surface water data, the depth interval of the sample in the water column must be specified. For sediment data (including chemistry, and benthic invertebrate toxicity and community data), sample depth interval must be identified and only sediment data collected from the depth interval of 0 to 15 cm (0 to 6 inches) below the sediment surface will be acceptable for inclusion in the risk assessments. Sediment collected from within a smaller portion of the depth interval of 0 to 15 cm will be considered for use in the risk assessments if the depth interval is representative of typical exposure depths for human and ecological receptors. Data from deeper sampling intervals may be evaluated for other aspects of the RI/FS but will not be considered for use in estimating potential risks.

Sample-Level DQO No. 2 – Sample and/or analysis type must be clearly identified. For tissue and surface water chemistry samples, the type of sample collected must be clearly identified. For example, sample type (e.g., fillet, carcass, whole body) must be specified for tissue samples; analysis type (e.g., filtered, unfiltered, total, dissolved)

[4] Includes dredged areas that have been backfilled with clean material.

and sample type[5] (e.g., transect, single point, depth of collection) must be specified for water samples. Information about the sample collection method (e.g., grab type, surface area of sediment sampled. and net size [for community data]) and sample processing method (e.g., screen size, preservation method) must be specified for benthic invertebrate toxicity and benthic invertebrate community samples.

3.4 RESULT LEVEL

Six result-level DQOs were identified:

Result-Level DQO No. 1 – Detection limits must be appropriately reported. For chemistry data, non-detected data must be reported with a numeric reporting limit (RL) and a U- or ND-qualifier. If no RL is reported, an effort will be made to obtain the RL from the laboratory.

Result-Level DQO No. 2 – Constituent parameters for summations must be available. For chemistry data, results of individual parameters included in chemical concentration sums (e.g., polychlorinated biphenyl [PCB] Aroclors, individual polycyclic aromatic hydrocarbons [PAHs]) must be reported. All sums (e.g., total PCBs, high-molecular-weight PAHs [HPAHs]) will be recalculated from the raw data collected by other parties to ensure that consistent rules regarding detection limits and summation are followed (see Section 4.1 for summation rules for risk assessment data). If specific constituent parameters of a sum are missing, partial totals will be calculated and flagged. The use of partial totals will be addressed in the uncertainty analysis in the risk assessments. Data sums for which individual component results are not available may be evaluated for other aspects of the RI/FS but will not be used in deriving risk estimates

Result-Level DQO No. 3 – Chemical analytical methods must be acceptable. Only data generated using USEPA-approved methods and/or other standardized methods (e.g., American Society for Testing and Materials [ASTM] methods), analyzed in accordance with properly prepared standard operating procedures (SOPs), and incorporated into work plans and/or QAPPs, will be considered for use in the risk assessments. Historical data for which chemical concentrations have been measured using low-resolution analyses will be evaluated on a case-by-case basis and per discussion with USEPA to determine whether it is appropriate to combine them with more recent data based on high-resolution analysis for evaluation in the risk assessments.

Result-Level DQO No. 4 – Toxicity and bioaccumulation test methods must be acceptable. For use in the risk assessments (specifically the BERA), toxicity and bioaccumulation test methods must have been based on standard toxicity or

[5] If water sample type is not reported as part of the electronic data, at a minimum, it must be available as part of the data report.

bioaccumulation test methods (e.g., ASTM and USEPA protocols). Negative controls must have been used in the tests, and the tests must meet the test-specific acceptability criteria provided in the ASTM or USEPA protocols. The sediment samples must have been stored prior to testing in accordance with ASTM and USEPA holding conditions.

Result-Level DQO No. 5 – Invertebrate community data must be reported to the lowest practical taxonomic level. Organisms in each sample must be identified to the lowest practical taxonomic level. Invertebrate community data should be reported on a per-sample basis; however, the use of summary statistics to describe sample-level characteristics may be considered on a case-by-case basis.

Result-Level DQO No. 6 – Benthic invertebrate community metric calculations must be documented. Individual metrics included in the dataset must be defined, and equations used to calculate biological indices must be provided. Alternatively, a citation that describes the method can be provided. Invertebrate community metrics should be reported on a per-sample basis; however, the use of summary statistics (e.g., mean abundance) to describe location-specific characteristics may be considered on a case-by-case basis.

3.5 VALIDATION LEVEL

While USEPA has no definitive guidelines specifying the level of data validation required for Superfund investigations, USEPA Order 5360.1 and OSWER Directive 9355.9-01 (USEPA 1993a) requires that environmental measurements be of known quality and be verifiable and defensible. The 2008 and 2009 QAPPs (Windward 2009a, b; ENSR et al. 2008) specify that validation should follow USEPA contract laboratory program national functional guidelines for organic and inorganic chemistry data (USEPA 1999, 2002b), and/or Region 2 modifications, to the extent they are applicable. Validation qualifiers have been assigned to chemistry data based on criteria in the Region 2 validation SOPs[6] or in the USEPA functional guidelines, whichever are more stringent. USEPA's information quality guidelines (USEPA 2002b) require that a dataset to be used for decision-making must be of known quality, legally defensible, and must have undergone the same level of scrutiny and review as any other environmental data generated internally or externally by or for USEPA.

Toxicity test, bioaccumulation test, and benthic community data also should undergo validation or verification, and these validation or verification results should be documented. Non-chemistry data may be used even if no validation was completed for the dataset provided that the data can be verified to meet USEPA acceptability criteria. Guidance regarding the validation and acceptability criteria of toxicity and bioaccumulation data is available as part of the standard test protocol (ASTM 2004,

[6] Region 2 validation SOPs are listed in Worksheet 36 of the 2008 and 2009 QAPPs (Windward 2009a, b; ENSR et al. 2008).

2007a, b, c; USEPA 2000) and typically includes verification requirements to ensure that tests are conducted within the test-specific parameters and that negative control specimens have acceptable survival rates. Taxonomic validation should be equivalent to USEPA's rapid bioassessment protocol guidelines for sorting and identification (Barbour et al. 1999).

Based on these guidelines, five validation-level DQOs were established for a dataset to be acceptable for use in the risk assessments:

Validation-Level DQO No. 1 – Chemistry data must be validated and include validation qualifiers, or sufficient information must be available to validate data. Laboratory qualifiers provide information about data quality. The application of data validation qualifiers consistent with USEPA functional guidelines (USEPA 1999, 2002b) and USEPA Region 2 validation SOPs, as specified in the 2008 and 2009 QAPPs (Windward 2009a, b; ENSR et al. 2008), allows data users to assess the quality of the data.

Validation-Level DQO No. 2 – Sufficient information must be available to confirm the quality of the biological test data. Consistent with Tables 11-2 and 11-3 of the 2009 Benthic QAPP (Windward 2009b), which describes data validation metrics and thresholds for benthic invertebrate toxicity and bioaccumulation tests; data validation of biological data includes the review of test conditions and quality assurance/quality control (QA/QC) data from the testing laboratory to determine if any test parameters would affect the interpretation of the biological results or potential uncertainties .

Validation-Level DQO No. 3 – Sufficient information must be available to confirm the quality and comparability of the taxonomic data. Information must be available to document the sampler type; sampler size, including surface area; sample depth; mesh size of the screen used to separate organisms from the sediment; sample preservation method; sample processing method, including subsampling; and level of taxonomic resolution in order to ensure the comparability of different datasets.

Validation-Level DQO No. 4 – Chemistry data reports must contain laboratory-generated forms (e.g., Form 1s) that include the results for each sample. Electronic chemistry data should be compared to Form 1s as a QC check to ensure that data generated by the laboratory have been accurately transferred to the LPRSA project database. If Form 1s are not available, some other laboratory-generated documentation must be available to conduct a QC check of laboratory-generated data against data reported in an electronic database.

Validation-Level DQO No. 5 – Existence and location of documentation supporting the dataset must be known. Existence and location of documentation supporting the dataset, including the analytical raw data and sample handling descriptions, must be known for future reference, confirmation, and reproducibility by a third party.

3.6 SUMMARY OF DQOS FOR EVALUATING RISK ASSESSMENT DATA

Table 3-1 lists the DQOs that will have to be satisfied for all data to be considered for inclusion in the LPRSA risk assessments. Data that do not meet the specified DQOs may be used in the evaluation of other aspects of the RI/FS (e.g., in the trend analysis), but will not be used in deriving risk estimates in the baseline risk assessments.

Table 3-1. Risk assessment DQOs for LPRSA data

Event Level
DQO No. 1 – Original hard copies or electronic copies of data report(s) must be available.
DQO No. 2 – Data must be representative of current conditions.
Station Level
DQO No. 1 – Sediment should not have been dredged[a] or capped.
DQO No. 2 – Field coordinates must be available to verify where data were collected.
Sample Level
DQO No. 1 – Sample depth interval must be identified.
DQO No. 2 – Sample and/or analysis type must be clearly identified.
Result Level
DQO No. 1 – Detection limits must be appropriately reported.
DQO No. 2 – Constituent parameters for summations must be available.
DQO No. 3 – Chemical analytical methods must be acceptable.
DQO No. 4 – Toxicity and bioaccumulation test methods must be acceptable.
DQO No. 5 – Invertebrate community data must be reported to the lowest practical taxonomic level.
DQO No. 6 – Benthic invertebrate community metric calculations must be documented.
Validation Level
DQO No. 1 – Chemistry data must be validated and include validation qualifiers, or sufficient information must be available to validate data.
DQO No. 2 – Sufficient information must be available to confirm the quality of the biological test data.
DQO No. 3 – Sufficient information must be available to confirm the quality and comparability of the taxonomic data.
DQO No. 4 – Chemistry data reports must contain laboratory-generated forms that include results for each sample.
DQO No. 5 – Existence and location of documentation that supports the dataset must be known.

[a] Includes dredged areas that have been backfilled with clean material.

CPG – Cooperating Parties Group

DQO – data quality objective

LPRSA – Lower Passaic River Study Area

4 Risk Assessment Data Reduction Rules

General data reduction rules for the tissue and sediment chemistry data collected in 2009 and 2010 have been established. These rules will be applied, as appropriate, to

data that will be used in the risk assessments to determine EPCs. The data reduction rules and additional rules for data reduction that are specific to the risk assessments are summarized in the following subsections.

4.1 CALCULATED TOTALS

Multiple totals will be presented in the LPRSA database based on multiple methods for treating RLs. However, for the risk assessments, only one total (derived using Rules 1 and 2, as appropriate) will be used in deriving risk estimates. Totals based on the following rules will be used for evaluation in the risk assessments:

- **Rule 1 (for non-toxicity-weighted totals)** – The total used in the risk assessments will be based on the sum of the detected constituent parameters (non-detected parameters will be treated as zeros); if none of the constituent parameters are detected, the total concentration will be flagged as non-detected (U-qualified) and represented as the highest RL. If any one of the constituent parameters is not reported, partial totals will be calculated and flagged. The use of partial totals will be addressed in the uncertainty analysis in the risk assessments.

  In order to ensure that the rule for determining non-toxicity-weighted totals is appropriate in the risk assessments, exposure estimates using totals based on the treatment of non-detects as zero, one-half the RL, and equal to the RL will be compared with one another to determine whether the treatment of non-detected parameters (as zero) affects exposure estimates. This evaluation will be included in the discussion of uncertainties associated with risk estimates.

- **Rule 2 (for toxicity-weighted totals) –** The toxicity-weighted total used in the risk assessments will be based on the sum of each constituent concentration multiplied by its corresponding toxic equivalency factor (TEF). The toxicity-weighted total used in the risk assessments will be based on the sum of the detected constituent parameters multiplied by their respective TEFs (non-detected parameters will be treated as zeros). If none of the constituent parameters within the toxicity-weighted total are detected, the total will be flagged as non-detected (U-qualified) and the TEQ value will be the highest toxicity-weighted reporting limit. If any one of the constituent parameters is not reported, partial totals will be calculated and flagged. The TEFs used to calculate TEQs for polychlorinated dibenzo-*p*-dioxins/ polychlorinated dibenzofurans (PCDDs/PCDFs) and dioxin-like PCB congeners for use in the BERA will be the World Health Organization (WHO) consensus values for fish and birds from Van den Berg et al. (1998). For the HHRA, the updated USEPA mammalian TEFs (USEPA 2010c) will be used to calculate TEQs. Carcinogenic PAH values will be calculated using TEF values (USEPA 1993b) based on the individual PAH component's toxicity relative to benzo(a)pyrene.

  In order to ensure that the rule for determining toxicity-weighted totals is appropriate in the risk assessments, exposure estimates using totals based on treatment of non-detects as zero, one-half the RL, and equal to the RL will be compared with one another to determine whether the treatment of non-detected parameters (as one-half the RL) affects exposure estimates. This evaluation will be included in the discussion of uncertainties associated with risk estimates.

Table 4-1 presents the constituent parameters for summations and risk assessment summation rules for LPRSA risk assessment data. The constituent parameters to be included in totals will be applied to all data that meet the acceptability criteria for use in developing risk estimates. The constituent parameters included in sums are consistent with the summations described in the *Fish/Decapod Crustacean Tissue and Benthic Sediment Data Management Plan* (ddms, in prep).

Table 4-1. Constituent parameters and risk assessment summation rules for LPRSA data

Parameter	Constituent Parameters	Risk Assessment Rule[a]
PCBs		
Total PCB congeners[b]	209 PCB congeners	Rule 1
Total PCB Aroclors[b]	Aroclor 1016, Aroclor 1221, Aroclor 1232, Aroclor 1242, Aroclor 1248, Aroclor 1254, Aroclor 1260, Aroclor 1262, and Aroclor 1268	Rule 1
PAHs		
Total HPAHs	benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoranthene,[c] benzo(g,h,i)perylene, benzo(k)fluoranthene, chrysene, dibenzo(a,h)anthracene, fluoranthene, indeno(1,2,3,-c,d)pyrene, and pyrene	Rule 1
Total LPAHs	acenaphthene, acenaphthylene, anthracene, fluorene, naphthalene, and phenanthrene	Rule 1
Total PAHs	acenaphthene, acenaphthylene, anthracene, benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoranthene,[c] benzo(g,h,i)perylene, benzo(k)fluoranthene, chrysene, dibenzo(a,h)anthracene, fluoranthene, fluorene, indeno(1,2,3,-c,d)pyrene, naphthalene, phenanthrene, and pyrene	Rule 1
Total benzofluoranthenes	benzo(b)fluoranthene,[c] benzo(k)fluoranthene	Rule 1
Carcinogenic PAHs	benzo(a)pyrene, benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, dibenz(a,h)anthracene, indeno (1,2,3-cd)pyrene, chrysene	Rule 2
Pesticides		
Total chlordanes	alpha-chlordane, gamma-chlordane, oxychlordane, cis-nonachlor, and trans-nonachlor	Rule 1
Total endosulfan	alpha-endosulfan (endosulfan I), beta-endosulfan (endosulfan II), and endosulfan sulfate	Rule 1
Total 4,4'-DDx	4,4'-DDD; 4,4'-DDE; 4,4'-DDT	Rule 1
Total 2,4'- and 4,4'-DDD	2,4'-DDD; 4,4'-DDD	Rule 1
Total 2,4'- and 4,4'-DDE	2,4'-DDE; 4,4'-DDE	Rule 1
Total 2,4'- and 4,4'-DDT	2,4'-DDT; 4,4'-DDT	Rule 1
Total DDx	2,4'-DDD; 2,4'-DDE; 2,4'-DDT; 4,4'-DDD; 4,4'-DDE; 4,4'-DDT	Rule 1
TEQ		
Total TEQ – mammal	Seventeen 2,3,7,8-substituted PCDD/PCDF congeners and twelve dioxin-like PCB congeners[d]	Rule 2
Total TEQ – bird	Seventeen 2,3,7,8-substituted PCDD/PCDF congeners and twelve dioxin-like PCB congeners[d]	Rule 2
Total TEQ – fish	Seventeen 2,3,7,8-substituted PCDD/PCDF congeners and twelve dioxin-like PCB congeners[d]	Rule 2

[a] Rule 1 – Use the sum of the detected constituent parameters only; non-detects will be treated as zeros. An evaluation will be conducted to determine whether the treatment of non-detected parameters (as zero) for non-

toxicity-weighted totals affects exposure estimates by comparing sums based on treatment of non-detects as zero, one-half of the RL, and equal to the RL in the uncertainty sections of the risk assessments.

Rule 2 – Use the sum of the concentration of each congener after multiplying by its corresponding TEF value. When the congener concentration is reported as non-detected, then multiply the TEF by one-half the RL. An evaluation will be conducted to determine whether the treatment of non-detected parameters (as one-half the RL) for toxicity-weighted totals affects exposure estimates by comparing sums based on treatment of non-detects as zero, one-half of the RL, and equal to the RL in the uncertainty sections of the risk assessments.

[b] For the risk assessments, total PCBs will be based on total PCB congeners (if available) or total PCB Aroclors (if PCB congener data are not available and total PCB Aroclors is deemed representative). When calculating a PCB congener sum, the concentration associated with a given co-elution will be included in the sum once.

[c] Benzo(j)fluoranthene, benzo(b/j)fluoranthene, and benzo(j/k)fluoranthene will also be included in the HPAH, total PAH, and total benzofluoranthene totals when reported.

[d] The twelve dioxin-like congeners are: PCB 77, PCB 81, PCB 105, PCB 114, PCB 118, PCB 123, PCB 126, PCB 156, PCB 157, PCB 167, PCB 169, and PCB 189.

DDD – dichlorodiphenyldichloroethane
DDE – dichlorodiphenyldichloroethylene
DDT – dichlorodiphenyltrichloroethane
HPAH – high-molecular-weight polycyclic aromatic hydrocarbon
LPAH – low-molecular-weight polycyclic aromatic hydrocarbon
LPRSA – Lower Passaic River Study Area
PAH – polycyclic aromatic hydrocarbon
PCB – polychlorinated biphenyl
PCDD – polychlorinated dibenzo-*p*-dioxin
PCDF – polychlorinated dibenzofuran
RL – reporting limit
TEF – toxic equivalency factor
TEQ – toxic equivalent
Total 4,4'-DDx – sum of 4,4'- substituted DDD, DDE and DDT
Total DDx – sum of all six DDT isomers (2,4′-DDD, 4,4-DDD, 2,4′-DDE, 4,4-DDE, 2,4′-DDT and 4,4′-DDT)

4.2 SELECTION OF SINGLE RESULT WHERE MULTIPLE RESULTS ARE REPORTED

In cases where multiple results are reported for a given sample, the risk assessments will use only one value so that every sample will be associated with one result per analyte. The rules for selecting the most appropriate result will be applied to all data that will be used in the risk assessments. The following subsections present the two cases wherein CPG will select a single sample result for use in the risk assessment: when multiple analytical methods are used for the analysis of the same chemical in a single sample (Section 4.2.1), and when multiple results are available due to QC analyses (Section 4.2.2).

4.2.1 Multiple analytical results for single sample

Multiple validated results for a given sample may be reported for specific analytes. When multiple results are reported for a single parameter, the most appropriate result will be flagged for reporting, analysis, and parameter summing, according to the best result selection rules for the LPRSA 2009 and 2010 CPG-collected data as described in the *Fish/Decapod Crustacean Tissue and Benthic Sediment Data Management Plan* (ddms, in prep):

- Analyte overlap will occur in the SVOC and PAH groups, and the high-resolution gas chromatography (HRGC)/high-resolution mass spectrometry (HRMS) or HRGC/low-resolution mass spectrometry results will take precedence. Specifically, the PAH HRGC/HRMS method results will take

precedence for 2-methylnaphthalene, acenaphthene, acenaphthylene, anthracene, benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoranthene, benzo(g,h,i)perylene, benzo(k)fluoranthene, chrysene, dibenzo(a,h)-anthracene, fluorene, indeno(1,2,3-cd)-pyrene, naphthalene, phenanthrene, and pyrene.

- Analyte overlap will occur in the SVOC and organochlorine pesticide groups (e.g., hexachlorobenzene). The HRGC/HRMS organochlorine results will take precedence over the SVOC results.

The selected best result (which is flagged) will be used in the risk assessments; unflagged result(s) will not be used.

4.2.2 Field duplicates and laboratory replicates

Field duplicates and/or laboratory QC analytical samples may result in more than one analytical result for field-collected samples. QC samples will be evaluated as part of the data validation process to ensure that QA/QC criteria are met. If QC samples are analyzed for a given field sample, only one value will be used in the LPRSA database.

Field duplicate results will be averaged with the parent sample result using the following rules:

- If both values are detected, the results will be averaged to determine a single result for inclusion in the LPRSA database.
- If a constituent is detected in only one sample, the detected value will be used.
- If a constituent is not detected in either sample, the result will be flagged as a non-detect (U-qualified), and the average of the two RLs will be used in the LPRSA database.

Lab replicate results will not be used in the LPRSA database; the value reported with the field sample will be used.

5 Risk Assessment Data Calculation Rules

Once all of the data for evaluation in the risk assessments have been identified and reduced, multiple risk-assessment-specific calculations will be needed for certain analyses in the risk assessments. These calculations may include the following:

- Organic carbon (OC)-normalizing sediment concentrations
- Lipid-normalizing tissue concentrations
- Reconstituting whole-body fish and crab concentrations

The risk assessments will also include calculations to determine descriptive statistics and measures of central tendency (e.g., upper confidence limit on the mean [UCL], mean) of chemical concentrations as part of the exposure assessments. The following

subsections present the rules for these risk assessment-specific data calculations. The HHRA will evaluate the reasonably maximum exposed (RME) individual, who is at the 90th percentile or above on the distribution of potential exposures, consistent with USEPA (1992b), and the central tendency exposure (CTE) individual, who represents average exposure. Details on how exposure estimates, including which statistics will be used to represent exposure estimates in the risk assessments, are described in the Revised RARC Plan (Windward and AECOM [in prep]).

5.1 NORMALIZATION

Both normalized and non-normalized data will be considered in the evaluation of biota-sediment accumulation factors. Normalization is a method for evaluating data trends, variability, and bioavailability. When applicable, lipid-normalized tissue concentrations and OC-normalized sediment concentrations will be calculated. The decision to normalize will be based on the demonstration of a linear or log-linear relationship between the chemical concentration and the normalizing variable. Non-normalized data will be evaluated in the bioaccumulation model.

Tissue concentrations that are lipid-normalized will be calculated on a sample-specific basis using the following equation:

$$C_{tis,lipid} = \frac{C_{tis,ww}}{f_{lipid}} \qquad \textbf{Equation 5-1}$$

Where:

$C_{tiss,lipid}$ = lipid-normalized tissue chemical concentration (mg/kg-lipid)
$C_{tiss,ww}$ = wet-weight tissue chemical concentration (mg/kg ww)
f_{lipid} = fraction lipid, wet-weight basis (% lipid/100)

Sediment concentrations that are OC-normalized will be calculated on a sample-specific basis using the following equation and the total organic carbon (TOC) data:

$$C_{sed,OC} = \frac{C_{sed,dw}}{f_{oc}} \qquad \textbf{Equation 5-2}$$

Where:

$C_{sed,OC}$ = OC-normalized sediment chemical concentration (mg/kg OC)
$C_{sed,dw}$ = dry-weight sediment chemical concentration (mg/kg dw)
f_{OC} = fraction organic carbon, dry-weight basis (%TOC/100)

5.2 CALCULATION OF WHOLE-BODY TISSUE CONCENTRATIONS

Chemical concentrations of whole-body tissues will be used in the BERA. Crab and some fish tissue collected during the late summer/early fall 2009 field effort were analyzed as individual tissue types (i.e., fish fillet, fish carcass, crab muscle and

hepatopancreas, and crab carcass) in order to support both the baseline HHRA and the BERA. In accordance with the Fish/Decapod QAPP (Windward 2009a), results for composites of the individual tissue types will be reconstituted as whole-body fish and crab samples based on the fraction of the whole-body mass represented by each tissue type.

Reconstituted whole-body fish tissue concentrations will be calculated using the following equation:

$$C_{WB} = (C_{fillet} \times f_{fillet}) + (C_{carcass} \times f_{carcass}) \qquad \textbf{Equation 5-3}$$

Where:

C_{WB} = estimated whole-body tissue concentration (mg/kg ww)
C_{fillet} = fillet tissue concentration (mg/kg ww)
f_{fillet} = fraction of whole-body weight that is fillet
$C_{carcass}$ = carcass tissue concentration (mg/kg ww)
$f_{carcass}$ = fraction of whole-body weight that is carcass (non-fillet)

Reconstituted whole-body (i.e., edible meat, hepatopancreas, and carcass) crab tissue concentrations will be calculated using the following equation:

$$C_{WB} = (C_{muscle+HP} \times f_{muscle+HP}) + (C_{carcass} \times f_{carcass}) \qquad \textbf{Equation 5-4}$$

Where:

C_{WB} = estimated whole-body soft tissue concentration (mg/kg ww)
$C_{muscle+HP}$ = muscle (edible meat) and hepatopancreas tissue concentration (mg/kg ww)
$f_{muscle+HP}$ = fraction of whole-body weight that is muscle (edible meat) and hepatopancreas
$C_{carcass}$ = carcass tissue concentration (mg/kg ww)
$f_{carcass}$ = fraction of whole-body weight that is carcass (non-muscle, non-hepatopancreas tissue)

For reconstituted whole-body concentrations that include a non-detected value for at least one tissue type, the non-detected value(s) will be represented in the calculation by one-half the detection limit. In cases where both tissue types are non-detected values, the final reconstituted whole-body result will be flagged as a non-detected result (U-qualified). The uncertainties associated with this assumption (i.e., the treatment of non-detected concentrations in reconstituting whole-body tissue concentrations) and the implications of using these data in the risk assessments will be evaluated and included in the uncertainty analysis of the risk assessments.

5.3 TREATMENT OF NON-DETECTS IN RISK CALCULATIONS

In the risk assessments, estimates of exposure will be based on an upper bound measure of central tendency identified as the UCL concentration. UCL concentrations will be calculated using ProUCL 4.1.00 (USEPA 2010a). Because ProUCL 4.1.00 includes provisions for handling non-detected data (USEPA 2010b), all data (detected and non-detected) will be used. For datasets of 5 to 10 samples, as agreed with USEPA, the UCL recommended by ProUCL will be used if it is below the maximum, and these instances will be identified in the text of the risk assessment. Details on how exposures will be estimated, including the statistics that will be used to represent the EPCs, are described in the Revised RARC Plan (Windward and AECOM [in prep]).

5.4 SIGNIFICANT FIGURES

Analytical laboratories will report results with various numbers of significant figures depending on the laboratory's SOPs, the instrument, chemical, and the reported chemical concentration relative to the RL. The reported (or assessed) precision of each result will be explicitly stored in the risk assessment database by recording the number of significant figures. Tracking of significant figures is important when calculating averages and performing other data summaries. The appropriate number of significant figures associated with specific risk estimates will be applied in the last step of each calculation, and will reflect the least precise value in the calculation (i.e., the lowest number of significant figures). Human health risks will be reported using one significant figure, consistent with USEPA Risk Assessment Guidance for Superfund, Part A (USEPA 1989).

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